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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,829	02/07/2002	Mark Douglas Howell	4369-1-1	4144

7590 04/19/2005

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,829

Applicant(s)

HOWELL ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50,51,60-65,69-74,80 and 81 is/are pending in the application.
- 4a) Of the above claim(s) 52-59,66-68 and 75-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50,51,60-65,69-74,80 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/7/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 50, 51, 60-65, 69-74, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skurkovich, 5,626,843, in view of Greenblatt, et al., "The type B receptor for tumor necrosis factor- α . mediates DNA fragmentation in HL-60 and U937 cells and differentiation in HL-60 cells", Blood, 1992, pp. 1339-46, Vol. 80.

Skurkovich '843 teaches the invention substantially as claimed,

More specifically, as to claim 50, Skurkovich '843 teaches a device for reducing the amount of a targeted immune system inhibitor in blood, comprising

an absorbent matrix comprising an inert medium (i.e., the immunosorbent, in col. 2, line 64; see also col. 4, line 7) attached to at least one binding partner (i.e., antibody in col. 2, line 65; see also col. 4, line 8) capable of specifically binding to a targeted immune system inhibitor,

and a conduit (i.e., input tube 14, col. 4, line 10) for conducting the blood to the absorbent matrix to produce altered blood having a reduced amount of the targeted immune system inhibitor (col. 4, 2, lines 61-65.)

As to claim 51, the targeted immune system inhibitor is present in a plasma component of the blood (col. 3, lines 53-55, and col. 4, lines 3-4.)

As to claim 80, a means for separating whole blood into cellular component and acellular component is disclosed in column 3, line 56.

As to claim 81, there is a means for providing a binding partner, comprising an absorbent matrix comprising an inert medium attached to a binding partner capable of specifically binding to the targeted immune system inhibitor (i.e., the immunosorbent, in col. 2, line 64; see also col. 4, line 7) attached to at least one binding partner (i.e., antibody in col. 2, line 65; see also col. 4, line 8).

Thus, Skurkovich '843 teaches removal of receptors for tumor necrosis factor (col. 3, lines 37-39; and claim 8, subsection b), using a binding partner such as a monoclonal or polyclonal antibody (col. 3, line 41; col. 2, line 65; see also col. 4, line 8), in order to restore immunity in some autoimmune diseases, such as AIDS (col. 1, lines 38-40; col. 2, lines 60-63; and claim 1, lines 1-2, claiming "a method of removing antigens from a patient with autoimmune disease or AIDS"; and claim 8, claiming that the method removes "at least one receptor for tumor necrosis factor".)

However, Skurkovich '843 does not specify that the binding partner binds to the receptor for tumor necrosis factor *alpha*. (Examiner notes that Applicant's claims are interpreted as if the receptor for tumor necrosis factor alpha and the receptor for tumor necrosis factor beta are two separate species in the Markush group.)

Greenblatt teaches that monoclonal antibodies against the receptor for tumor necrosis factor alpha are known (see abstract.)

It would have been obvious to one of ordinary skill in the art to utilize the antibody against the receptor for tumor necrosis factor alpha taught by Greenblatt as the antibody binding partner in the Skurkovich '843 invention because Skurkovich teaches removal of receptors to tumor necrosis factor receptors in general and one would use the appropriate reagent, in this case the antibody of Greenblatt, to remove the desired analytes.

As to claims 61 and 63, the binding partner or fragment (i.e., the antibody taught by Greenblatt) is capable of being produced recombinantly. (Examiner notes that even though Applicant claims that the binding partner is produced recombinantly, Applicant is claiming a device; and therefore the claim is examined as if it was a product-by-process claim. Therefore the prior art meets the claim since the Greenblatt antibody may be produced recombinantly.)

As to claim 60, the binding partner is a binding partner to which the targeted immune system inhibitor binds to in nature, or a fragment of the binding partner to which the targeted immune system inhibitor binds to in nature, wherein the fragment specifically binds to the targeted immune system inhibitor (see Greenblatt abstract.)

As to claim 62, the binding partner is a monoclonal antibody or a fragment of a monoclonal antibody that specifically binds to the targeted immune system inhibitor (see Greenblatt abstract.)

As to claim 64, the binding partner comprises a plurality of different monoclonal antibodies or fragments thereof, wherein the plurality are capable of specifically binding

to the targeted immune system inhibitor (Skurkovich teaches a plurality of antibodies on an immunosorbent, col. 5, line 4, and Greenblatt teaches the specific antibody claimed.)

As to claim 65, the binding partner comprises a plurality of different monoclonal antibodies or fragments thereof, wherein the monoclonal antibodies or fragments thereof are collectively capable of specifically binding to a plurality of targeted immune system inhibitors (Skurkovich teaches a plurality of antibodies on an immunosorbent, col. 5, line 4, and Greenblatt teaches the specific antibody claimed.) (Examiner notes that claiming a plurality of different antibodies does not necessarily claim a plurality of different *types* of antibodies, which appears to be what Applicant is claiming. In any case, Skurkovich '843 teaches a plurality of different types of antibodies on an immunosorbent.)

As to claims 69 and 73, the binding partner may be produced synthetically. (Examiner notes that even though Applicant claims that the binding partner is a synthetic peptide, Applicant is claiming a device; and therefore the claim is examined as if it was a product-by-process claim. Therefore the prior art meets the claim since the Greenblatt antibody may be produced synthetically.)

As to claims 70 and 72, the synthetic peptide is conjugated to a carrier (i.e., the immunosorbent in Skurkovich '843.)

As to claims 71 and 74, the binding partner comprises a plurality of synthetic peptides capable of specifically binding to the targeted immune system inhibitor (Skurkovich '843 teaches a plurality of antibodies in the immunosorbent.)

2. Claims 50, 51, 60, 61, 66-74, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skurkovich, 5,626,843, in view of Yelavarthi et al., "Analysis of p60 and p80 tumor necrosis factor-.alpha", American Journal of Pathology, 1993, pp. 1131-41, Vol. 143.

Skurkovich '843 teaches the invention substantially as claimed.

More specifically, as to claim 50, Skurkovich '843 teaches a device for reducing the amount of a targeted immune system inhibitor in blood, comprising

an absorbent matrix comprising an inert medium (i.e., the immunosorbent, in col. 2, line 64; see also col. 4, line 7) attached to at least one binding partner (i.e., antibody in col. 2, line 65; see also col. 4, line 8) capable of specifically binding to a targeted immune system inhibitor,

and a conduit (i.e., input tube 14), col. 4, line 10) for conducting the blood to the absorbent matrix to produce altered blood having a reduced amount of the targeted immune system inhibitor (col. 4, 2, lines 61-65.)

As to claim 51, the acellular component or the fraction of the acellular component is a plasma component or fraction thereof (col. 4, lines 3-4, disclosing that the device is capable of use with blood.) Examiner notes that Applicant is claiming a device and that the device is for use with blood or blood components. Thus, the Skurkovich '843 device meets the claims since the device is capable of use with plasma, or acellular component of blood. In any case, it is unclear as to what Applicant is claiming in claim 51, since claim 51 recites a limitation that has been canceled from claim 50, from which it depends, and thus has not antecedent basis for the limitation.

As to claim 80, a means for separating whole blood into cellular component and acellular component is disclosed in column 3, line 56.

As to claim 81, there is a means for providing a binding partner, comprising an absorbent matrix comprising an inert medium attached to a binding partner capable of specifically binding to the targeted immune system inhibitor (i.e., the immunosorbent, in col. 2, line 64; see also col. 4, line 7) attached to at least one binding partner (i.e., antibody in col. 2, line 65; see also col. 4, line 8).

Thus, Skurkovich '843 teaches removal of receptors for tumor necrosis factor (col. 3, lines 37-39; and claim 8, subsection b), using a binding partner such as a monoclonal or polyclonal antibody (col. 3, line 41; col. 2, line 65; see also col. 4, line 8), in order to restore immunity in some autoimmune diseases, such as AIDS (col. 1, lines 38-40; col. 2, lines 60-63; and claim 1, lines 1-2, claiming "a method of removing antigens from a patient with autoimmune disease or AIDS"; and claim 8, claiming that the method removes "at least one receptor for tumor necrosis factor".)

However, Skurkovich '843 does not specify that the binding partner binds to the receptor for tumor necrosis factor *alpha*. (Examiner notes that Applicant's claims are interpreted as if the receptor for tumor necrosis factor alpha and the receptor for tumor necrosis factor beta as two separate species in a Markush group.)

Yelavarthi teaches that polyclonal antibodies against the receptor for tumor necrosis factor alpha are known (see Yelavarthi abstract disclosing that "[t]ranslation was verified in all samples by immunohistol. using polyclonal antibodies specific for the receptor proteins.")

It would have been obvious to one of ordinary skill in the art to utilize the antibody against the receptor for tumor necrosis factor alpha taught by Yelavarthi as the antibody binding partner in the Skurkovich '843 invention because Skurkovich teaches removal of receptors to tumor necrosis factor receptors in general and one would use the appropriate reagent, in this case the antibody of Yelavarthi to remove the desired analyte.

As to claim 61, the binding partner or fragment (i.e., the antibody taught by Yelavarthi) is capable of being produced recombinantly. (Examiner notes that even though Applicant claims that the binding partner is produced recombinantly, Applicant is claiming a device; and therefore the claim is examined as if it was a product-by-process claim. Therefore the prior art meets the claim since the Yelavarthi antibody may be produced recombinantly.)

As to claims 60 and 66, the binding partner is a binding partner to which the targeted immune system inhibitor binds to in nature, or a fragment of the binding partner to which the targeted immune system inhibitor binds to in nature, wherein the fragment specifically binds to the targeted immune system inhibitor (see Yelavarthi abstract.)

As to claims 67 and 68, the binding partner comprising a plurality of different polyclonal antibody preparations (Skurkovich teaches a plurality of antibodies on an immunosorbent, col. 5, line 4, and Yelavarthi teaches the specific antibody claimed.)

As to claims 69 and 73, the binding partner may be produced synthetically. (Examiner notes that even though Applicant claims that the binding partner is a synthetic peptide, Applicant is claiming a device; and therefore the claim is examined as

if it was a product-by-process claim. Therefore the prior art meets the claim since the Yelavarthi antibody may be produced synthetically.)

As to claims 70 and 72, the synthetic peptide is conjugated to a carrier (i.e., the immunosorbent in Skurkovich '843.)

As to claims 71 and 74, the binding partner comprises a plurality of synthetic peptides capable of specifically binding to the targeted immune system inhibitor (Skurkovich '843 teaches a plurality of antibodies in the immunosorbent.)

3. Claims 52, 54, 58, 83-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skurkovich, 5,626,843, in view of Greenblatt, et al., "The type B receptor for tumor necrosis factor- α . mediates DNA fragmentation in HL-60 and U937 cells and differentiation in HL-60 cells", Blood, 1992, pp. 1339-46, Vol. 80, and further in view of Skurkovich 4,362,155.

Skurkovich '843 in view of Greenblatt discloses the invention substantially as claimed, see above with respect to claim 50.)

Although Skurkovich '843 does not teach a blood cell separator in the '843 patent itself, Skurkovich '843 discloses that substances can be obtained with an extracorporeal device from whole blood, using a blood cell separator to which the immunosorbent column is connected (col. 3, lines 53-57.) Skurkovich '843 specifically discloses that such a device is known from U.S. Patent 4,362,155, and incorporates by reference the '155 patent (col. 3, lines 58-59.)

Patent '155 teaches an apparatus (58) for separating whole blood into a cellular component and an acellular component or a fraction of the acellular component, (col. 4, lines 33, and lines 35-39) as claimed by Applicant in claim 83.

As to claim 84, Patent '155 teaches that the acellular component or fraction thereof contains the targeted immune system inhibitor (col. 4, lines 37-41.)

As to claim 85, the conduit conducts the acellular component or fraction thereof to a absorbent matrix (60) to produce an altered acellular component or altered fraction thereof having a reduced amount of the targeted immune system inhibitor (col. 4, lines 38-41.) Patent '155 also teaches that the device (60) is a sorbent containing device, which can be the means (14) for removing interferon, or a device for a method of using a sorbent for interferon carried by a solid support (col. 4., lines 38-44.)

As to claim 86, the system further comprises a conduit (62) for conducting the altered acellular component or fraction thereof from the absorbent matrix to the cellular component to produce an altered whole blood (col. 4, lines 45-49.)

It would have been obvious to one of ordinary skill in the art to use the apparatus for separating whole blood into a cellular component and an acellular component or a fraction of the acellular component as disclosed in Patent '155 with the immunosorbent column in the Skurkovich '843 device since Skurkovich '843 explicitly states that the blood cell separator disclosed in Patent '155 can be used with the immunosorbent column. Moreover, both Skurkovich '843 and Patent '155 teach an apparatus and method for removing antigens from blood and returning the altered blood to a patient to treat an autoimmune disease (see preamble of claim 1 of Patent '155), and Patent

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'155 also teaches that the separator can be used with any suitable sorbent (col. 4, lines 40-44.)

Furthermore, as to claims 52 and 54, Skurkovich does not specify that the immunosorbent comprise macroporous beads.

Patent '155 teaches that the sorbent containing device can be means (14) (col. 4, lines 39-40.) Means (14) includes beads (28), (col. 3, lines 54-59), which remove interferon (col. 4, lines 8-9.)

It would have been obvious to one of ordinary skill in the art that the immunosorbent in the Skurkovich '843 device can be a sorbent containing beads since Patent '155 teaches that a solid support for removing interferon or antigens (col. 3, lines 9-12) can be beads.

Also as to claim 58, the inert medium is a silica-based particle (28.) (Glass is known to be silica-based.)

4. Claims 50, 53, 55-57 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skurkovich, 5,626,843, in view of Greenblatt, et al., "The type B receptor for tumor necrosis factor- α mediates DNA fragmentation in HL-60 and U937 cells and differentiation in HL-60 cells", Blood, 1992, pp. 1339-46, Vol. 80, further in view of Skurkovich 4,362,155, and further in view of Prusiner et al., 6,221,614.

Skurkovich '843 in view of Greenblatt and further in view of Patent '155 teaches the invention substantially as claimed (see above with respect to claim 50.)

Moreover, Skurkovich '843 teaches that the extracorporeal device includes an immunosorbent (col. 2, line 64.) Skurkovich '843 explicitly states the extracorporeal device is more specifically disclosed in Patent '155.

Patent '155 teaches an apparatus and method for removing antigens from blood and returning the altered blood to a patient to treat an automimmune disease (see preamble of claim 1 of Patent '155.) Patent '155 also teaches the use of a separator and teaches that the separator can be used with any suitable sorbent (col. 4, lines 40-44), such as beads (col. 4, lines 40-42, and col. 3, line 59.)

However Patent '155 does not specifically teach that the inert medium is a hollow fiber (claim 53), a cellulose-based fiber (claim 55), a synthetic fiber (claim 56), or a flat membrane (claim 57), or that the binding partner is covalently joined to an inert medium (claim 59.)

Prusiner, like Skurkovich '843 and Patent '155, also teaches an extracorporeal device to remove material from blood through complexing with an immobilized agent on a support (col. 8, lines 42-51), wherein the immobilized agent may be an antibody (col. 15, lines 37-38.) Prusiner, similar to Patent '155, teaches that the support may be beads ((col. 8, line 50.) Prusiner further teaches that the support may be of other types, such as a membrane (col. 8, line 50.) The support is considered the inert medium claimed by Applicant.

As to claim 53, Prusiner secifically teaches that the inert medium is a hollow fiber (col. 13, line 50.)

As to claim 55, Prusiner teaches that the inert medium may be a cellulose-based fiber (col. 16, line 13.)

As to claim 56, the fiber may be produced synthetically. (Examiner notes that Applicant claims that the fiber is a synthetic fiber. However, since Applicant is claiming a device, the claim is interpreted as if it was a product-by-process claim. Thus, the prior art meets the claim since the fiber may be produced synthetically.)

As to claim 57, Prusiner teaches that the inert medium may be a flat membrane (col. 13, lines 48-49.)

It would have been obvious to one of ordinary skill in the art to provide a hollow fiber, cellulose-based fiber, or flat membrane as taught by Prusiner as the immunosorbent in the Skurkovich '843 device since they are immunosorbents known to be an alternative to beads, as taught by Prusiner. Moreover, covalent couplings between an antibody and a support are well known in the art, and thus the choice of materials for covalent couplings would be obvious to one of ordinary skill in the art.

Moreover, as to claim 59, Prusiner teaches that the safest coupling between a complexing agent and a membrane is covalent coupling, which depends on the choice of membrane material and the nature of the complexing agent (col. 15, lines 58-67.)

It would have been obvious to one of ordinary skill in the art to provide, in the Skurkovich '843 immunosorbent, a membrane and complexing agent that would allow for covalent coupling as would be desirable for safe coupling as taught by Prusiner.

Response to Arguments

As a preliminary matter, Examiner would like to clarify the status of claim 80. Applicant states that Applicant believes the rejection of claim 80 is in error since claim 80 was withdrawn due to the election. Examiner would like to clarify that claim 80 is not considered withdrawn. In the last Office action, Examiner rejected claim 80 as being obvious, but then Examiner inadvertently rejected claim 81 under 112 as being vague for depending from withdrawn claim 80 (this 112 rejection has now been withdrawn). To clarify the matter, claim 80 is not considered withdrawn, since it is a generic claim, as stated in the restriction requirement. Since the elected species (the absorbent matrix in claims 50-74, 81 and 83-86) were not found to be allowable, Examiner therefore prosecutes claim 80, the generic claim, along with the elected species. Examiner would apologize for the confusion.

Applicant's arguments filed February 7, 2005 have been fully considered but they are not persuasive.

Applicant has amended the claims to, inter alia, remove the limitation, "soluble receptors for interferon γ " from the original claims, and argues that the claims thus now exclude the removal of interferon. Applicant further states that the Skurkovich invention requires the removal of interferon and as such there is no motivation to stimulate an immune response in the absence of removal of interferon (i.e., there is no motivation to not remove interferon.)

Examiner asserts that Skurkovich does not require the removal of interferon. Skurkovich in column 3 lines 1-4, discloses sorbents that do not have interferon (see

"other sorbents" in line 2.) Likewise, in column 3, lines 22-23, Skurkovich discloses an example of treating an autoimmune disease such as rheumatoid fever wherein one sorbent is used for removing interferons and a second sorbent is for removing antibodies against cardiac tissue. Furthermore, column 3, lines 37-39 teaches removal of "IFNs, TNF, and HLA II class antigen, and/or their receptors". Because Skurkovich uses the term "or", Skurkovich teaches removal of the receptors by itself. Thus, the sorbents in the Skurkovich disclosure do not always require binding agents that remove interferon, contrary to Applicant's argument.

In any case, contrary to Applicant's argument, the amended claims do not exclude the removal of interferon. The claims recite a "system....comprising...." Thus, even though the Markush group does not list interferon as one of the immune system inhibitor to which a binding partner is capable of binding, the claims do not exclude interferon because the claims use the open term, "comprising".

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641
4/16/05